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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/083,576	02/27/2002	Linda H. Malkas	38761-77811	5889

7590 06/08/2005

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EXAMINER	
HUFF, SHEELA JITENDRA	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 06/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/083,576	Malkas et all	
	Examiner	Art Unit	
	Sheela J. Huff	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-8 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-8 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 10/22/02.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

S.O.O.

DETAILED ACTION

Claims 1-8 are pending.

Information Disclosure Statement

The IDS filed 10/22/02 has been considered and an initialed copy of the PTO-1449 is enclosed.

Claim Rejections - 35 USC § 112

Claims 1-8 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the purification and detection of breast cancer specific PCNA, does not reasonably provide enablement for the purification and detection of any cancer-specific PCNA. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Applicant claims and discloses the purification and detection of cancer-specific PCNA in a sample. As stated by applicant on page 10, lines 10-17 of the specification, the particular cancer is not critical and that it includes cancers such as cervical carcinoma, mammary gland carcinoma, stomach and ovarian cancer. However, as disclosed in Tomic et al, Proc. American Assn. For Cancer research, Abstract No. 2507, vol. 42 page 466 (3/01), the only PCNA that can be detected using XPG is the acidic form of PCNA which is specific for breast cancer cells. Even applicant's own specification (page 3) discloses the csPCNA is specific for breast cancer cells. Furthermore, the only examples provided in the specification are those using breast

cancer cells. No examples have been provided to show that the csPCNA can be found in cancers other than breast. Thus, it appears that the type of cancer is critical.

In view of the above, it is the Examiner's position that undue experimentation would be required by one skilled in the art to use the claimed invention.

Claim Objections

Claim 8 is objected to because of the following informalities: In claim 8, line 3 "immunobilization" should be --immobilized--.. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 4-5 are rejected under 35 U.S.C. 102(a) as being anticipated by Tomic et al, Proc. American Assn. For Cancer research, Abstract No. 2507, vol. 42 page 466 (3/01) as evidence by Gary et al JBC vol. 272 p. 24522 (1997).

This reference discloses an immunoassay (ELISA) specific for the detection of the acidic form of PCNA (ie the assay distinguishes between PCNA and the acidic form of PCNA (which is csPCNA)). The assay detects the binding of csPCNA to XPG. As evidenced by Gary et al, SEQ ID NO. 1 (of claim 4) is a portion of XPG (see p. 24523,

second column, lines 20-21). It is inherent that the ELISA used an antibody labeled with a detectable enzyme.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 4-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tomic et al, Proc. American Assn. For Cancer research, Abstract No. 2507, vol. 42 page 466 (3/01) in view of Gary et al JBC vol. 272 p. 24522 (1997) and Knott et al US 6514703 (filed 7/3/01).

Tomic et al and Gary et al have been discussed above.

The only difference between the instant invention and the references is the specific mention of an antibody labeled with a detectable enzyme where the enzyme is horse radish peroxidase, the peptide in the assay is a fusion protein of peptide and glutathione-S-transferase and wherein the fusion protein is biotinylated and the solid support is streptavidin-coated.

Gary et al disclose the fusion protein of glutathione-S-transferase-peptide XPG (p. 24522-23).

Knott et al disclose ELISA for the detection of breast cancer is known and that there are a variety of different variations that are encompassed by ELISA and that the enzymes for labeling antibodies are known in the art and horse radish peroxidase (HRP) is specifically mentioned (col. 6, lines 53-54). On col. 11, lines 65+ the reference disclosed the use of the biotinylated fusion protein in an ELISA and the use of streptavidin-coated plates.

Therefore, in view of the known use of a variety of difference detectable enzymes in the ELISA, it would have been obvious to one of ordinary skill in the art at the time of applicant's invention to use HRP in the ELISA of the primary reference. As shown by Knott et al, the use of biotinylated fusion proteins in ELISA with streptavidin coated

plates is also well known in the art and that there are a variety of different variations on ELISA and in view of the numberous variations in ELISA it also would have been obvious to modify the ELISA of the primary reference using biotinylated fusion proteins in ELISA with streptavidin coated plates.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheela J. Huff whose telephone number is 571-272-0834. The examiner can normally be reached on Mondays and Thursdays from 5:30am to 2:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sheela J Huff
Primary Examiner
Art Unit 1642

sjh